UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL NO. 1456
LITIGATION)
) CIVIL ACTION: 01-CV-12257-PBS
)
THIS DOCUMENT RELATES TO:) Judge Patti B. Saris
ALL CLASS ACTIONS)

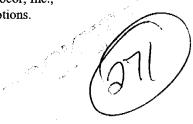
PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO MOTION TO STRIKE PARAGRAPHS 155-56 OF THE MASTER COMPLAINT AND MOTION FOR A MORE DEFINITE STATEMENT FROM CERTAIN PARAGRAPHS OF THE MASTER COMPLAINT

Plaintiffs, by their undersigned counsel, submit this Memorandum in opposition to the motions of defendants Schering-Plough Corporation ("Schering") and Warrick Pharmaceuticals ("Warrick") to strike paragraphs 155-56 of the Master Consolidated Class Action Complaint ("Complaint") and for a more definite statement from certain paragraphs of the Complaint.

I. INTRODUCTION AND BACKGROUND

Schering and Warrick¹ have filed motions pursuant to Fed. R. Civ. P. 12(e) and (f) to strike two paragraphs of the Complaint relating to a recent guilty plea of another drug manufacturer, TAP Pharmaceuticals, Inc. ("TAP"), for AWP manipulation and other conduct identical to the schemes alleged in the Complaint and for a more definite statement in the certain paragraphs of the Complaint where the phrases "Defendants" or "Defendant Drug Manufacturers" are used.

¹ Defendants Abbott Laboratories, Johnson & Johnson, Ortho Biotech Products, L.P., Centocor, Inc., Merck & Co., Inc., Sicor, Inc. and Gensia Sicor Pharmaceuticals, Inc. have joined in the Motions.



Schering and Warrick contend that references to the TAP guilty plea should be stricken because they are immaterial and prejudicial. However, as detailed below, the references to TAP's guilty plea and \$875 million dollar payment to the federal and state governments counter the Defendants' main argument about prior knowledge and approval of AWP manipulation. The guilty plea and other information contained in paragraphs 155 and 156 of the Complain negate Defendants' assertion that everyone knew that AWP's bore no resemblance to actual pricing and the federal government condoned this fraud. Thus, the TAP guilty plea references are properly within the Complaint and should not be stricken.

Schering and Warrick also contend that references in the Complaint to "Defendants" and "Defendant Drug Manufacturers" are so vague that Defendants are unable to "frame an answer, evaluate grounds for a motion to dismiss, compose initial disclosures, or propound or resist discovery." *See* Def. Mem. at p. 2. Schering and Warrick go so far as to brazenly assert that the Complaint is so deficient in framing the issues that "the Court cannot effectively preside over these proceedings" absent greater specificity from Plaintiffs (*Id.*).

Initially, Plaintiffs note that Schering and Warrick's claims are significantly undermined by the fact that, as noted in the Complaint at paragraphs 315-316, Schering and Warrick are currently being sued by the Attorney General of Texas, and Warrick and Abbott (who joined in the motions) are being sued by the Attorney General of West Virginia for the same type of AWP manipulation alleged by Plaintiffs in this litigation. Given these pending cases, it is difficult to believe that Schering, Warrick and the other Defendants cannot understand the allegations made against them in the Complaint.

Further undermining Schering and Warrick's position is the fact that all Defendants, including Schering and Warrick, have filed initial disclosures and all Defendants have filed motions to dismiss which comprehensively address the *substance* of the Complaint's allegations. Schering and Warrick have joined in the Consolidated Motion to Dismiss. Apparently, the Defendants were able to understand the Complaint well enough to submit over 100 pages of briefing on the Complaint's alleged deficiencies as to why their manipulation of the AWP system was well known and even approved by the federal government.

Plaintiffs demonstrate in their Consolidated Opposition to Defendants' Motion to Dismiss ("Opposition") filed concurrently herewith, that the Complaint adequately outlines the fundamental nature and scope of Plaintiffs' case so as to enable each of the Defendants to articulate and frame their defenses. There is no basis or need for the unusual and exceptional remedy requiring a more definite statement under Rule 12(e).

The Complaint sets forth a scheme in which each of the Defendants intentionally and fraudulently inflated the Average Wholesale Price ("AWP") of various pharmaceuticals they manufacture for the purpose of deceiving Plaintiffs and the Classes into overpaying for these drugs. The Complaint identifies how each Defendant, including Schering and Warrick, have participated in the fraudulent schemes.

As detailed below, striking allegations or requiring a more definite statement are disfavored remedies that go against modern pleading trends of notice pleading and discovery. Schering and Warrick claims of prejudice and incomprehensibility ring hollow, and do not require the extreme and drastic remedies being sought.

II. ARGUMENT

A. Defendants' Motion To Strike References in the Complaint to the TAP Plea Agreement Is Premature and Should Be Denied

Defendants seek to strike from the Complaint all references to the TAP plea agreement, invoking Fed. R. Civ. P. 12(f), which provides, in relevant part, that "the court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent or scandalous matter."

"Rule 12(f) motions have not been commonplace . . . in this Circuit . . ." Ashey v. Lily Transportation Corp., 2001 WL 705804 at *1 (D.Me. June 18, 2001). Indeed, the Court of Appeals for the First Circuit has observed that such "motions are narrow in scope, disfavored in practice and not calculated readily to invoke the court's discretion." Boreri v. Fiat, S.P.A., 763 F.2d 17, 23 (1st Cir. 1986). "Courts disfavor the motion to strike, because it proposes a drastic remedy." Ashey, 2001 WL 705804 at *1 (quoting 2. Moore, et al., Moore's Federal Practice § 12.37[1] (3d ed. 2000)). Moreover, "[M]otions [under Rule 12(f)] are generally disfavored and will usually be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties." Demoulis v. Sullivan, 1993 WL 81500 *6 (D. Mass. Feb. 26, 1993). See generally Kounitz v. Slaaten, 901 F. Supp. 650, 658 (S.D.N.Y. 1995) ("motions to strike are generally disfavored and will not be granted unless the matter asserted clearly has no bearing on the issue in dispute").

The allegations that Schering and Warrick want stricken appear at paragraphs 155 and 156, and relate to the recent prosecution of TAP for illegally manipulating the AWP system. Paragraph 155 briefly summarizes and describes how the AWP system was abused and manipulated by TAP.

These allegations are relevant to Plaintiffs' position that manipulation of the AWP system was not, as the Defendants assert in their motion to dismiss, known and tolerated for years by the federal and state governments. The circumstances surrounding TAP's prosecution and payment of \$875 million are thus appropriately included in the Complaint to illustrate the fallacy of the Defendants' contention that this case should be dismissed because the manipulation of the AWP system has been known and condoned by the government. The allegations about TAP also serve to illustrate a recent well-publicized abuse of the system and the manner in which a drug company so inclined can illegally manipulate the system.

Paragraph 156, which is also proposed to be stricken, quotes Judge William G. Young of this Court and his statement that TAP's conduct was "a gross abuse of the Medicare/Medicaid repayment system..." Schering and Warrick boldly state that the Complaint "does not allege that any Defendant in this proceeding participated with TAP in any of the conduct that gave rise to the criminal conviction... nor that any Defendant was... a target of the remarks quoted." Defs.' Mem at p. 3. In reality, as Schering and Warrick well know, Defendant Abbott owns and controls 50 percent of TAP and was intimately involved in the criminal prosecution and settlement. Certainly Abbott, who joined in Schering and Warrick's motion, was aware of its role and participation in the TAP litigation.

Defendants Schering and Warrick have not satisfied, nor can they satisfy, the exacting burden of demonstrating their entitlement to the extraordinary remedy of having paragraphs 155 and 156 stricken from the Complaint. They suffer no prejudice from

having these allegations remain in the Complaint.² The exceptional and highly disfavored remedy of a motion to strike these allegations as immaterial or prejudicial under Rule 12(f) is therefore unwarranted and out of place at this threshold stage of the litigation. Defendants' motion to strike these allegations under Rule 12(f) should be denied.

B. The Complaint Places Defendants On Notice of the Claims Asserted In Sufficient Detail To Allow Them To Frame A Responsive Pleading

Defendants Schering and Warrick have also moved for a more definite statement pursuant to Fed. R. Civ. P.12(e), which provides, in relevant part, that "[i]f a pleading to which a responsive pleading is permitted is so vague or ambiguous that a party cannot reasonably be required to frame a responsive pleading, he may move for a more definite statement before interposing his responsive pleading." Defendants contend that the Complaint does not adequately apprise them of their alleged participation and role in the wrongdoing asserted in the Complaint, and that many allegations are made against "Defendants" or "Defendant Drug Manufacturers".

In reality, Schering and Warrick are trying to turn the Plaintiffs' careful efforts to avoid duplicative pleading into an excuse to avoid liability. A closer examination reveals that many of the cited paragraphs either plainly encompass all Defendants (Complaint ¶¶1-8, 135-140), or explicitly states that the allegation relates to "each" of the Defendant Drug Manufacturers (Complaint ¶¶459, 463). The allegations that members of the non-profit association Plaintiffs purchased drugs from the Defendant Drug Manufacturers,

² One of the other Defendants, Bristol-Meyers Squibb, has gone so far as to declare that the federal government itself could not even pursue a claim for AWP manipulation. BMS Memorandum in Support of Motion to Dismiss, p.14. The fact of the TAP settlement reveals this defense argument to be false and further supports denial of the motion to strike.

(Complaint ¶¶ 28-49), are intended to and do allege that a member of each association purchased at least one drug from each defendant.³

Federal Rule of Civil Procedure 8(a)(2) requires only a "short and plain statement of the claim showing that the pleader is entitled to relief." A unanimous Supreme Court recently reaffirmed the continued vitality of that admonition, "[t]he liberal notice pleading of Rule 8(a) is the starting point of a simplified pleading system, which was adopted to focus litigation on the merits of a claim." *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 513-14 (2002).

In Raytheon Co. v. Continental Casualty Co., 123 F. Supp. 2d 22, 26-27 (D.Mass. 2000)(Saris, J.) this Court held that:

Plaintiffs only are obliged to set forth in their complaint "factual allegations either direct or inferential, regarding each material element necessary to sustain recovery under some actionable legal theory." Gooley v. Mobil Oil Corp., 851 F.2d 513, 515 (1st Cir. 1988). The Rules "do not require a claimant to set out in detail the facts upon which he bases his claims." Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit, 507 U.S. 163, 168, 113 S. Ct. 1160, 122 L. Ed.2d 517 (1993) (internal citation omitted). "[T]he issue is not whether the Plaintiff will ultimately prevail, but whether that party is entitled to offer evidence to support its claims." Day v. Fallon Community Health Plan, Inc., 917 F. Supp. 72, 75 (D. Mass.1996).

A motion for a more definite statement under Rule 12(e) is only appropriate in the extreme case when a complaint is "wholly barren of specifics." *United States v. SCRAP*, 412 U.S. 669, 689-90 n. 15. (1973) "Rule 12(e) motions are designed to strike at unintelligibility, rather than at lack of detail in the complaint . . . Therefore, a [R]ule

³ See Exhibits 3 through 26 of Affidavit of Thomas M. Sobol in Support of Plaintiffs' Opposition to Defendants' Motions to Dismiss the Master Consolidated Class Action Complaint, filed simultaneously herewith.

12(e) motion is properly granted only when a party is unable to determine the issues he must meet." Cox v. Maine Maritime Academy, 122 F.R.D. 115, 116 (D. Me. 1988).⁴
Where a complaint generally places a Defendant on notice of the nature of the claims against it, a Rule 12(e) motion should be denied. As this Court has observed in denying a Rule 12(e) motion:

While Defendants may prefer highly detailed factual allegations, a generalized statement of facts is adequate so long as it gives the Defendant sufficient notice to file a responsive pleading. . . . It is only if the complaint 'is so vague or ambiguous that a party cannot reasonably be required to frame a responsive pleading' that a more definite statement is needed. The degree of detail sought by [Defendant] exceeds pleading requirements and is information that can be obtained through discovery. . . . [Plaintiff] has alleged sufficient facts to put [Defendant] on notice of the claims against it.

Raytheon Co., 123 F. Supp. 2d at 33 (quoting Langadinos v. American Airlines, Inc., 199 F.3d 68, 72-73 (1st Cir. 2000)). See generally Fease v. Town of Shrewsbury, 188 F.Supp.2d 16, 17 (D.Mass. 2002) ("Courts do not invoke Rule 12(e) frequently . . ."); Cox, 122 F.R.D. at 116 ("Rule 12(e) motions are not favored by the Courts in light of the availability of pretrial discovery procedures."); Iacampo v. Hasbro, Inc., 929 F. Supp. 562, 571 (D.R.I. 1996)("Rule 12(e) is rarely invoked . . . ").

The Complaint herein adequately apprises all Defendants, including Schering and Warrick, of the nature and scope of Plaintiffs' claims, and the general role of all

⁴ Accord Delta Educ., Inc. v. Laglois, 719 F.Supp. 42, 50 (D.N.H. 1989)("[a] more definite statement will be required only when the pleading is so vague or ambiguous that the opposing party cannot respond even with a simple denial, in good faith or without prejudice to himself.") Town of Hooksett School District v. W.R. Grace & Co., 617 F. Supp. 2d 126, 135 (D.N.H. 1984)(denying motion to strike under Rule 12(e)("[t]he Defendant has enough information on the circumstances of the alleged fraud and conspiracy to reasonably be expected to frame an answer . . .").

Defendants in the illegal scheme to manipulate the AWP system.⁵ Schering and Warrick's objection to Plaintiffs' allegations referring generally to all "Defendants" is without merit. This case involves widespread and systematic abuses of the AWP system by each of the Defendants, including Defendants Schering and Warrick, in a substantially similar, if not identical manner. The Complaint outlines the method in which the AWP system was abused and does so in a manner that is neither vague nor ambiguous. No further differentiation is appropriate, warranted or necessary at this time to allow Schering and Warrick to frame their fundamental defenses to the Complaint.⁶

1. The "Schering -Plough Group"

Schering and Warrick also profess confusion over Plaintiffs' use of the term "the Schering-Plough Group". The Complaint recognizes that Schering and Warrick are separate corporate entities, but also states that Warrick is Schering's wholly owned subsidiary, and has been since Warrick was created in 1993. (Complaint ¶122.) Thus, Schering clearly controls Warrick's actions and activities.

The Defendants' argument is further undermined by the fact that several of the Defendants are currently the subject of governmental investigations about AWP manipulation, See BMS' Form 10-Q for the period ending June 30, 2002, "We, together with a number of other pharmaceutical manufacturers, also have received subpoenas and other document requests from various government agencies seeking records relating to its pricing and marketing practices for drugs covered by Medicare and/or Medicaid. The requests for records have come from, the United States Attorney's Office for the District of Massachusetts, the Office of the Inspector General of the Department of Health and Human Services in conjunction with the Civil Division of the Department of Justice, and several states. We are producing documents and actively cooperating with these investigations, which could result in the assertion of criminal and/or civil claims. We are unable to assess the outcome of these investigations, which could include the imposition of fines, penalties and administrative remedies."

⁶ See generally Cox, 122 F.R.D. at 117 (denying motion for a more definite statement, reasoning that "[t]he fact that the complaint does not identify in which specific incidents Defendant Proulx is alleged to have been involved does not necessarily entitle Proulx to a more definite statement. . . . Paragraph 14, though skeletal, is pleaded so as reasonably to allow Defendant Proulx to respond, knowing whether or not he was involved in any or none of the incidents there charged Under federal notice pleading no greater detail seems to be required, and the parties must be left to other pretrial devices to expedite and simplify the proceedings.").

The relationship between the two companies is further proven by the fact that both maintain the same counsel in this litigation, and the Motions to Strike and For a More Definitive Statement were filed by both parties jointly. As with many of the other issues raised in their Motions, Schering and Warrick's protestations about being lumped together are completely undercut by the fact of their decision to jointly use the same counsel and their own simultaneous actions.

III. CONCLUSION

The remedies Schering and Warrick seek harken back to days of formalized pleadings and limited discovery. As another Court has recently noted:

The Federal Rules of Civil Procedure have long departed from the era when lawyers were bedeviled by intricate pleading rules and when lawsuits were won or lost on the pleadings alone. Thus the courts should not tamper with the pleadings unless there is a strong reason for so doing. Evidentiary questions, such as the one present in this case, should especially be avoided at such a preliminary stage of the proceedings. Usually the questions of relevancy and admissibility in general require the context of an ongoing and unfolding trial in which to be properly decided. And ordinarily neither a district court nor an appellate court should decide to strike a portion of the complaint--on the grounds that the material could not possibly be relevant--on the sterile field of the pleadings alone.

Ashey, 705804 at **1-2.

For the foregoing reasons, the motion of Defendants Schering and Warrick to strike paragraphs 155-56 of the Complaint and for a more definite statement should be denied.

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By b DA

DATED:

December 5, 2002.

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CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused a true and correct copy of the foregoing Plaintiffs' Memorandum of Law in Opposition to Motion to Strike Paragraphs 155-56 of The Master Complaint and Motion For a More Definite Statement From Certain Paragraphs of The Master Complaint to be served on all counsel of record electronically on December 5, 2002, pursuant to Section D of Case Management Order No. 2.

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